



MAR 17 1999

Food and Drug Administration
Rockville MD 20857**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

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Satish R. Shah
66 Lockwood Place
Clifton, NJ 07012

Re: Docket No. 93N-0349

Dear Mr. Shah:

The Food and Drug Administration (FDA) has completed its evaluation of your Application for Special Termination of your permanent debarment. As you were informed by letter on December 10, 1997, FDA will not consider an application for special termination of debarment unless an applicant first clearly establishes that he or she provided *substantial assistance* in the investigations or prosecutions of certain offenses. This is a matter of law, and the Agency has no discretion whatsoever in this regard. Without a clear showing of substantial assistance, the Agency cannot terminate a debarment. An applicant must not merely assert that he or she provided substantial assistance, but must present independent evidence of substantial assistance.

In your original application (Exhibit 1) and supplements to the application, you discussed the basis for your claim of having provided substantial assistance to the government, and enclosed letters from Gary Tunkavige and Thomas Holland.¹ Mr. Tunkavige states that "information provided by Mr. Shah, combined with information developed from other sources, contributed to the evidence of misconduct on the part of individuals associated with Par Pharmaceutical, Inc." (Exhibit 2 at 2). Mr. Holland states that "Mr. Shah took the initiative in contacting the authorities and continued to cooperate in the investigation" (Exhibit 3 at 1). Mr. Tunkavige's dealings with you predate the prosecution of Par and individuals from Par. Mr. Holland confirmed by telephone that he dealt with you solely before any indictments were issued, and that he was not involved in your prosecution.

On May 5, 1993, you were convicted by jury trial² of two Federal felonies: conspiracy to commit an offense against the United States and aiding and abetting false statements to a Federal agency (Exhibit 4). FDA contacted the Department of Justice (DoJ) to obtain additional information about your convictions. Lawrence McDade, Deputy Director of the Office of Consumer

¹ Mr. Tunkavige is a Senior Safety Officer with the FDA and is the Lead Investigator for an inspection of your former employer, Par Pharmaceutical, Inc. (Exhibit 2 at 1). Mr. Holland is a special agent in the Office of the Inspector General, U.S. Department of Health and Human Services (Exhibit 3 at 1).

² In FDA's experience, defendants who provide substantial assistance to the government are typically convicted under plea agreements, so as not to expend government resources on a matter in which guilt is uncontested.

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about your convictions. Lawrence McDade, Deputy Director of the Office of Consumer Litigation at DoJ, informed by Chris Mead and Ray Bonner, the former Assistant United States Attorneys (AUSA) who prosecuted your case, notified FDA by letter that although you initially provided some truthful information about illegal Par activities, you also provided false information to DoJ and were involved in a scheme to extort funds from Par in return for not providing certain information to DoJ (see Exhibit 5).

You state further in your application that you were "the victim of [a] government cover-up with FDA," and that your attorney was incompetent to represent you (Exhibit 1 at 1). The district court and the Fourth Circuit Court of Appeals fully considered and dismissed as not relevant the facts underlying the claim that you were a victim of a government cover-up.³ Similarly, your claims about ineffective counsel were previously addressed.⁴ Neither claim substantiates your assertion that you provided substantial assistance to the government.

The above information demonstrates that you indeed provided some assistance to the government, but were not completely truthful in your disclosures and did not fully cooperate with the government. To provide assistance to the government, an informant's information, including responses to questions, need to be truthful.⁵ Although you provided some truthful information to

³ You submitted as part of your application a letter you wrote to the Office of Professional Responsibility (OPR) at DoJ in which you claim that the U.S. Attorney's Office violated the Proffer made between you and that office (Exhibit 6 at 1). You note, however, that the U.S. Attorney's Office told you that you had "breached such agreement and the government was not precluded from using the information that [you] had provided" (Exhibit 6 at 2). As noted in OPR's response to your letter (Exhibit 7 at 1), the Fourth Circuit Court of Appeals held that your claims of assistance to the government were irrelevant to the jury's finding of your guilt:

Shah desired to enter evidence that he voluntarily came forth with the evidence that led to this and other prosecutions and that the FDA "appreciated" his help. While these contentions might have been true, they were wholly irrelevant to Shah's guilt. Because they were irrelevant, they were properly excluded. (Exhibit 8 at 2).

Moreover, the Proffer you signed states that you were not entitled to immunity from prosecution (Exhibit 9). In the course of the general prosecution of Par and Par employees, the government discovered that you had not disclosed all of your own illegal actions while a Par employee and the government prosecuted you for these actions. This prosecution, therefore, was not a violation of the terms of the Proffer and there appears to have been no "cover-up."

⁴ You claim that OPR "determined that in fact my trial attorney was at fault and incompetent to represent me during the trial" (Exhibit 1 at 2), but you did not include a copy of the response you received from OPR. In fact, OPR simply informed you that "[s]uch claims are not appropriate for the Department of Justice's consideration" and recommended that you contact the state bar or the court clerk for further assistance. (Exhibit 7 at 1).


⁵ The Federal Food, Drug, and Cosmetic Act does not define the term "substantial assistance." However, the phrase is used in the context of the sentencing guidelines. See, e.g., *United States v. Avellino*, 136 F.3d 249 (2d Cir. 1998) (discussing the government's discretion to evaluate a defendant's assistance and the government's right to terminate a cooperative agreement where the defendant lies to the government).

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FDA and to DoJ, the quality of your assistance was marred by untruthfulness. Therefore, the Agency does not find that you provided substantial assistance to the government. First, you did not provide complete or wholly truthful information to the government. Second, you did not take responsibility for your own crimes, which meant the government had to expend significant government resources to prosecute you.

The Agency finds that you did not provide substantial assistance in the investigations or prosecutions of generic drug offenses. Your application for special termination of debarment is therefore denied.

Sincerely yours,


for Gary J. Dykstra
Acting Associate Commissioner
for Regulatory Affairs

Exhibits

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EXHIBITS

- Exhibit 1 April 28, 1997 Letter from Satish Shah to Michael Friedman, FDA
- Exhibit 2 January 9, 1998 Letter from Gary Tunkavige
- Exhibit 3 February 20, 1998 Letter from Thomas Holland
- Exhibit 4 Judgment
- Exhibit 5 May 28, 1998, Letter from DoJ to FDA
- Exhibit 6 July 24, 1995 Letter from Satish Shah to Michael Shaheen, Jr., DoJ
- Exhibit 7 January 17, 1997 Letter from Candice Will, OPR, to Satish Shah
- Exhibit 8 *United States v. Shah*, No. 93-5397 (4th Cir. Oct. 19, 1994) (per curiam)
- Exhibit 9 October 16, 1989 Proffer